K090095

510(k) Summary

MAR 13 2009

1. Date of Summary

December 11, 2008

2. 510(k) Applicant

Broncus Technologies, Inc.
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3. Device Overview

Trade Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) System

Common Name: Picture Archiving and Communications Systems

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050
Product Code LLZ

4. Predicate Device

The predicate device identified for the LungPoint VBN is as follows:

Trade Name	510(k) Submitter	510(k) Number
superDimension®/Bronchus inReach™ System	superDimension, Ltd	K080271, cleared on March 31, 2008
superDimension/Bronchus	superDimension, Ltd	K042438, cleared on November 8, 2004

5. Device Description

This premarket notification covers Broncus' LungPoint VBN System. The VBN System is a software only device, providing a navigation system to help the bronchoscopist plan

and proceed to a predefined target site in the tracheobronchial tree. Specifically, the VBN system provides global guidance to targets preselected by the bronchoscopist in peripheral airways. In doing so, the VBN can provide local guidance to lymph nodes to enable tissue sampling. It can also facilitate the return to an exact location in the lungs that had previously been treated for assessment of or continued therapy.

The VBN software is installed on an off-the-shelf PC computer system, and is intended to be used with commercially-available flexible bronchoscopes with HRCT scans that are saved in DICOM format.

6. Intended Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint VBN software is substantially equivalent to the predicate. The VBN software has the same intended use and similar technological characteristics as the predicate. The difference in technological characteristics, specifically the navigation method of the VBN software, does not raise any new questions of safety or effectiveness.

8. Performance Data

An animal study was conducted to evaluate the accuracy of the VBN system during bronchoscopic follow-up procedures in a canine model. Accuracy was assessed by determining the mean and standard deviation of the distance error between the virtual targets defined in the virtual rendering and the actual target in the real bronchoscope video. The results of the study indicate that the distance error of the VBN system is 2.17 +/- 0.84 mm.

The results of the animal study corroborated the outcome of an earlier phantom study performed by Merritt et al, which showed that the mean and standard deviation of the distance error of the VBN system is 2.2 +/- 2.3 mm.

9. Safety and Effectiveness

The VBN labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the software. Risk management is ensured via a hazard analysis and FMEA, which are used to identify potential hazards. These potential hazards are controlled via software development, verification testing and validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2009

Broncus Technologies, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K090095
Trade/Device Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: February 19, 2009
Received: February 20, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090095

Device Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software

Indications for Use: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-CounterUse _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090095